JUL 2 4 2003

Special 510(k)
Myotronics-Noromed, Inc

510(k) SUMMARY

Model J-5 Myo-monitor

510(k) # K031998

Myotronics-Noromed, Inc.
15425 – 53rd Avenue South
Tukwila, WA 98188
Telephone (206) 243-4214
Contact: Mr. Fray Adib, President

June 24, 2003

Device: Model J-5 Myo-monitor

Legally marketed predicate device: Model J-4 Myo-monitor (K842223) Myotronics-Noromed, Inc.

Description of the Device: The device is an ultra-low frequency, battery operated muscle stimulator used to relax the muscles of the head and neck. It is capable of stimulating either two or four muscle groups at once.

Intended Use: Used to relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain, to relax muscles and establish a physiologic occlusion, to take occlusal registrations, to take denture impressions, to increase local blood circulation and to increase or maintain mandibular range of motion.

Comparison with predicate device: The Model J-5 Myo-monitor has exactly the same intended uses and fundamental technology as its predecessor, the Model J-4 Myo-monitor. The design change which is the subject of this premarket notification is to add an additional pair of stimulating channels with separate controls. This permits treatment of four muscle sites simultaneously as opposed to the two muscle site capability of the predecessor device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

Ms. Fary Adib
President
Myotronics Noromed, Incorporated
15425 53rd Avenue South
Tukwila Washington 98188

Re: K031998
Trade/Device Name: Model J-5 Myo-Monitor
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: KZM
Dated: June 24, 2003
Received: July 8, 2003

Dear Ms. Adib

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

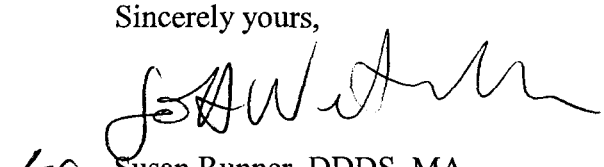
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Susan Runner, DDDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031998

Device Name: Model J-5 Myo-monitor

INDICATIONS FOR USE

- To treat Temporomandibular Joint (TMJ) dysfunction and associated pain
- To relieve symptoms associated with muscle spasm
- To relax muscles and establish a physiologic occlusion
- To take occlusal registrations
- To take denture impressions
- To increase local blood circulation
- To maintain or increase mandibular range of motion

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031998

Prescription Use XX OR Over-The-Counter Use _____
(Per 21 CFR 801.109)